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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

MUMMERT, STEPHANIE KANE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/655,579

Applicant(s)

PARK ET AL.

Examiner

Stephanie K. Mummert

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 and 3-8, drawn to a composition comprising one or more anti-DNA polymerase or anti-reverse transcriptase antibodies and at least one SSB, classified in class 424, subclass 130.1.
 - II. Claims 2 and 15-20, drawn to a composition comprising at least two different single strand binding proteins, classified in class 530, subclass 350.
 - III. Claims 9-14 and 21-23, drawn to a method of nucleic acid synthesis comprising a mixture of one or more antibodies and one or more single strand binding proteins, classified in class 435, subclass 6.
 - IV. Claims 11 and 21-22, drawn to a method of nucleic acid synthesis comprising a mixture of two or more single stranded binding proteins, classified in class 435, subclass 91.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II, IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to distinct compositions which are not related to each other. The composition of group I is directed to a composition which comprises one or more anti-DNA polymerase or anti-reverse transcriptase antibodies and at least one single stranded binding protein, while the composition of

Art Unit: 1637

group II is directed to a composition which comprises at least two single stranded binding proteins. The method of group IV is directed to the synthesis of nucleic acids using the composition of group II. While both compositions include single stranded binding proteins, the composition of group I does not require more than one single strand binding protein. Therefore, prior art directed to the composition of group I that included only one single strand binding protein would not address the composition of group II or the use of the composition in the method of group IV. Therefore, these compositions are distinct and unrelated and should not be searched together because in order to search these compositions and the method together would require distinct searches which are not coextensive and to require a search of these inventions together would pose an undue burden on the examiner.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the composition of group I can be used in the detection of a DNA polymerase or reverse transcriptase enzyme in a Western blot or in an immunofluorescence assay. Therefore, because the composition of group I can be used in techniques which are distinct from a method of nucleic acid synthesis, it would be necessary to search the composition of group I separately from the method of group III and these separate searches would encompass distinct terms and most likely distinct fields within the prior art. Therefore, to require a search of both of these inventions together would pose an undue burden on the examiner.

Art Unit: 1637

4. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to distinct inventions which are not disclosed as capable of use together. The method of group III requires a composition comprising one or more single stranded binding proteins and antibodies directed against DNA polymerase or reverse transcriptase, while the composition of group II requires the use of at least two different single strand binding proteins. The method does not use the composition of group II and prior art directed to one would not necessarily address the other. Therefore, these inventions are distinct and independent and to require a search of both together would pose an undue burden on the examiner.

5. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the composition of group II can be used in a DNA binding or gel-shift assay or the composition could be used in hybridization detection assays. Therefore, because the composition of group II can be used in techniques which are distinct from a method of nucleic acid synthesis, it would be necessary to search the composition of group II separately from the method of group III and these separate searches would encompass distinct terms and most likely distinct fields within the prior art. Therefore, to require a search of both of these inventions together would pose an undue burden on the examiner.

Art Unit: 1637

6. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to distinct methods that require the use of different reagents, different starting materials and different method steps. The method of group III is directed to a method which requires the use of antibodies and one or more single stranded binding proteins, while the method of group IV requires the use of two or more single stranded binding proteins. While both methods include single stranded binding proteins, the method of group III does not require more than one single strand binding protein. Therefore, prior art directed to the method of group III that included only one single strand binding protein would not address the method of group IV. Therefore, these methods are distinct and unrelated and should not be searched together because in order to search these methods together would require distinct searches which are not coextensive and to require a search of these inventions together would pose an undue burden on the examiner.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

Art Unit: 1637

inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

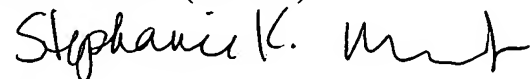
Art Unit: 1637

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie K. Mummert whose telephone number is 571-272-8503. The examiner can normally be reached on M-F, 8:30-5.

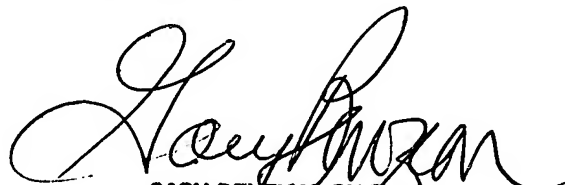
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Stephanie K Mummert
Examiner
Art Unit 1637

SKM



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SUPERVISORY PATENT EXAMINER
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